Effectiveness of drainage of the kidney by percutaneous nephrostomy catheter placement versus retrograde double J catheter placement in patients with symptoms of obstructive kidney disease caused by uroithiasis.

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The primary objective is to assess whether a PCN is non-inferior to double J catheter regarding time to clinical recovery in patients with obstructive kidney disease resulting from urolithiasis.As the secondary objective we would like to investigate...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Urolithiases
Study type	Observational non invasive

Summary

ID

NL-OMON52865

Source
ToetsingOnline

Brief title
STONE study

Condition

- Urolithiases

Synonym
nierstenen, Urolithiasis

Research involving

Human

Sponsors and support

Primary sponsor: Alrijne ziekenhuis namens de Nederlandse Vereniging voor Urologie
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: double J catheter, kidney, percutaneous nephrostomy catheter, urolithiasis

Outcome measures

Primary outcome

The primary outcome parameter is time to clinical recovery.

Clinical recovery is defined as reaching one or more of the following criteria.

The mandatory amount of criteria to achieve clinical recovery is dependent on

the indication for placement of a PCN or a JJ (e.g. if the indication for

placement is infection and pain, one is considered clinically recovered if the

criteria for infection and pain is reached).

- Infection: improvement of infection, indicated by a decrease of WBC in two

executive laboratory results and below 15.000 mm3 and a body temperature of

36-38.5 C, with no recurrence of a temperature outside of these boundries

within 24 hours if measured.

and/or

- Pain: NRS considering pain resulting from a renal colic is improved and < 3

points

and/or

- Kidney function: improvement of creatinine/GFR in two executive laboratory

results

Secondary outcome

As the secondary objective we would like to investigate if there is any

difference in PROMS and societal costs between the PCN arm and the JJ arm.

Secondary outcomes are further clinical data, PROMS (measured by the EQ-5D-5L,

NRS, a satisfaction scale and further disease specific questions) and societal

costs (measured by a disease-specified iMCQ questionnaire).

Study description

Background summary

Urolithiasis is a common disease. If a stone obstructs the ureter and impairs urine-efflux from the kidney this may cause infection, pain resulting from a renal colic and/or renal impairment. Pyelonephritis combined with obstruction can result in a life-threatening sepsis. Renal impairment may become chronic if the obstruction is not treated adequately.
For these reasons, quick recovery of urinary passage with an adequate drainage method is essential. This can be done by direct stone removal, but this may be contra-indicated in case of infection, or not feasible for other reasons. In this case there is choice between placement of a percutaneous nephrostomy catheter (PCN) or double J catheter (JJ).
Advocates of JJ support this choice because of a better quality of life and possible complications resulting from placement of a PCN (obstruction, dislocation). Besides, a double J catheter might be arranged easier at their institute. Advocates of PCN use comparable arguments: a PCN catheter gives less trouble for the patient and can be placed more easily. In addition urine production by the affected kidney can be monitored. A double J catheter has complications as well (dislocation, infection, obstruction).
Combining drainage method, setting (outpatient or inpatient), room in which drainage procedures takes place (treatment room versus operating room, OR) and anesthesia method there are in fact 16 different approaches for drainage available, each with its own patient and cost-perspectives. If we want to offer these patients the most (cost-)effective treatment in a uniform and evidence-based way, first and foremost we must know if PCN is non-inferior to JJ regarding clinical recovery. In addition, we have to know which setting

offers most comfort to the patients, and the costs of both procedures in the different settings.

Study objective

The primary objective is to assess whether a PCN is non-inferior to double J catheter regarding time to clinical recovery in patients with obstructive kidney disease resulting from urolithiasis.

As the secondary objective we would like to investigate if there is any difference in PROMS and societal costs between the PCN arm and the JJ arm.

Study design

A multicenter prospective randomized controlled non-inferiority trial comparing percutaneous nephrostomy catheter placement with double J catheter placement including a cost-effectiveness study.

Study burden and risks

The placement of either PCN or double J catheter is standard care. Currently the choice for PCN or a double J catheter is based on expert opinion and may be driven by arguments considering logistics or assumptions about the quality of life for a patient after placement and does not seem to be evidence based. Considering the difference in rate of placement of both PCN and double j catheter between various hospitals and different countries, it is believed experts have not come to a uniform work method to handle the dilemma of choosing between these two techniques. Furthermore the current EAU-guideline 2018 states that both methods of drainage are to be considered as equal. Therefore there is no reason to believe, patients will be affected negatively by being placed randomly in either the double J group or the PCN group. Questionnaires will be filled in daily during hospitalization and twice or less afterwards. This is not considered to be a risk for the patient. The longest questionnaires questionnaire (EQ-5D-5L and iMCQ) will take approximately 10-20 minutes to fill in, additional to the shorter scales (NRS, satisfaction scale) which will take approximately 1 minute to fill in. Generally It will take 90 minutes, spread over the course of three months, to fill in all questionnaires. When final treatment of urolithiasis has taken place, questionnaires will no longer have to be filled in. Finally, no additional visits to a hospital, withdrawal of blood samples or exposure to radiation is to be expected when taking part in this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Male/female >18 years
- Symptoms and/or laboratory results indicating obstructive kidney disease with or without infection.
- A kidney or ureteral stone is present on ultrasound or CT (max 3 months old prior to presentation)
- Both drainage techniques are feasible and safe (from logistics point of view as well as in the best interest of the patient) in opinion of the treating physician
- Coagulation status is acceptable for both procedures, possibly corrected by additional medication
- Willing and able to comply with filling in questionnaires and follow-up

regiment.

Exclusion criteria

- Analphabetic or not mastering the Dutch language
- Pregnancy
- Contraindication for either technique looking at history and anatomy (e.g. kidney transplant, pouch, Bricker deviation, urethral or ureteral stenosis)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-06-2020
Enrollment:	204
Type:	Actual

Ethics review

Approved WMO

Date:	22-01-2020
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO
Date: 17-06-2020

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Approved WMO
Date: 11-09-2020

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Approved WMO
Date: 24-05-2021

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Approved WMO
Date: 24-02-2022

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO
Date: 17-10-2022

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO
Date: 30-01-2023

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 22950
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL70822.058.19
Other	NL8128
OMON	NL-OMON22950